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
**PCT**

**NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

(PCT Rule 72.2)

To:

SCHRELL, Andreas  
Leltzstrasse 45  
70469 Stuttgart  
ALLEMAGNE

Date of mailing (day/month/year) 16 December 2004 (16.12.2004)		
Applicant's or agent's file reference 25096 WO	21. DEZ. 2004	IMPORTANT NOTIFICATION
International application No. PCT/EP2003/003533	Bearbeiter: 	International filing date (day/month/year) 04 April 2003 (04.04.2003)
Applicant CYTONET GMBH & CO. KG et al		

**1. Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

**2. Transmittal of the copy of the translation to the elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

AZ, CA, CH, CN, CO, GH, KG, KP, KR, MK, MZ, RU, TM

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, BA, BB, BG, BR, BY, BZ, CR, CU, CZ, DK, DM, DZ, EA, EC, EE, EP, ES, FI, GB, GD, GE, GM, HR, HU, ID, IL, IN, IS, JP, KE, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MN, MW, MX, NI, NO, NZ, OA, OM, PH, PL, PT, RO, SC, SD, SE, SG, SK, SL, TJ, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

**3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

**It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.**

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Translation

PATENT COOPERATION TREATY

PCT/EP2003/003533



# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 25096 WO	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP2003/003533	International filing date (day/month/year) 04 April 2003 (04.04.2003)	Priority date (day/month/year) 06 April 2002 (06.04.2002)
International Patent Classification (IPC) or national classification and IPC C12Q 1/68		
Applicant CYTONET GMBH & CO. KG		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.  
  
☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  
  
These annexes consist of a total of 6 sheets.
3. This report contains indications relating to the following items:
  - I ☒ Basis of the report
  - II ☐ Priority
  - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

Date of submission of the demand 05 November 2003 (05.11.2003)	Date of completion of this report 02 July 2004 (02.07.2004)
Name and mailing address of the IPEA/EP  Facsimile No.	Authorized officer  Telephone No.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP2003/003533

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☐ the international application as originally filed
- ☒ the description:  
pages 1-56, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages 1-19, filed with the letter of 07 April 2004 (07.04.2004)
- ☒ the drawings:  
pages 1/4-4/4, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

**I. Basis of the report**

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

5.

One of the amendments submitted with the letter of 5 April 2004 introduces substantive matter which goes beyond the disclosure of the international application as filed. This pertains to the following amendment in claims 2, 3 and 17: "plasmid containing at least one sequence selected from Seq. Id. No. 14, Seq. Id. No. 15, Seq. Id No. 16 and Seq. Id. No. 17". There is no basis in the application for a plasmid that contains more than one of the indicated sequences. This report is therefore established without taking this amendment into account.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP2003/003533

## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 2, 3, 18 (all in part)

because:

- ☐ the said international application, or the said claims Nos. \_\_\_\_\_  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 2, 3, 18 (all in part)  
are so unclear that no meaningful opinion could be formed (*specify*):

See the Supplemental Sheet.

- ☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for said claims Nos. \_\_\_\_\_

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
- ☐ the computer readable form has not been furnished or does not comply with the standard.

## Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1.

Claims 2 and 3 are unclear because it has not been defined in what way the 16S-rRNA fragments of the synthetic plasmid are "modified".

Further, claim 18 is unclear because the relative term "genus-specific region III" has no generally recognized meaning and leaves the reader uncertain as to the meaning of the technical feature affected, especially as item c) in claim 18 indicates only one single primer for amplification of this region.

inferred from the cited prior art that the claimed detection technique by means of melting curve analysis makes it possible to produce a more specific detection of mycobacterial infection than with known prior art methods, at the same time identifying pathogens of the *Mycobacterium tuberculosis* complex and/or of *Mycobacterium avium*. The hybridization probes as well as control plasmids used in the claimed method are specific to this method because even the slightest sequence deviations would result in a strong influence on the melting temperature; they can therefore be considered inventive.